

HOUSE BILL REPORT

HB 3064

As Reported by House Committee On:
Environmental Health, Select

Title: An act relating to providing safe collection and disposal of unwanted drugs from residential sources through a producer managed and funded product stewardship program.

Brief Description: Creating a producer managed and funded product stewardship program to collect and dispose of unwanted residential drugs.

Sponsors: Representatives Morrell, Green, Appleton, Seaquist, VanDeWege, Upthegrove, Lantz, Kenney, Roberts, Simpson, Hunt, O'Brien, Linville, Ormsby, Wood, Campbell, Jarrett and Hudgins.

Brief History:

Committee Activity:

Select Committee on Environmental Health: 1/23/08, 1/30/08 [DPS].

Brief Summary of Substitute Bill

- Establishes a product stewardship program for the collection, transportation, and disposal of unwanted drugs from residential sources.

HOUSE SELECT COMMITTEE ON ENVIRONMENTAL HEALTH

Majority Report: The substitute bill be substituted therefor and the substitute bill do pass. Signed by 8 members: Representatives Campbell, Chair; Hudgins, Vice Chair; Sump, Ranking Minority Member; Chase, Hunt, Morrell, Newhouse and Wood.

Staff: Brad Avy (786-7289).

Background:

Unless unwanted drugs from residential sources are properly disposed of, they can lead to accidental poisonings, illegitimate access to drugs that can lead to abuse, and contamination of surface and groundwater from medicine that is flushed down toilets or thrown in the garbage.

The Washington State Department of Health's Board of Pharmacy (WSBP), the U.S. Drug Enforcement Administration, and the Washington Department of Ecology (DOE) regulate

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pharmaceutical waste in Washington. The DOE is involved only when the pharmaceutical is disposed of as waste.

A pilot program put together by a coalition of government and non-profit groups is currently underway in the Puget Sound region. It is modeled after a similar program in British Columbia to collect and properly dispose of unwanted pharmaceutical products from residential sources.

Summary of Substitute Bill:

Every producer of covered products sold in or into the state must participate in a product stewardship program for unwanted products from residential sources by January 1, 2010. Covered products include both brand name and generic drugs. Producers must:

- operate, either individually or collectively with other producers, a product stewardship program approved by the WSBP; or
- enter into an agreement with a stewardship organization to operate, on the producer's behalf, a product stewardship program approved by the WSBP; or
- pay all the administrative costs and operational costs associated with their product stewardship program, including the cost of the collection, transportation, and disposal of the unwanted products that are collected from residential sources and the recycling or disposal, or both, of its packaging;
- provide product stewardship programs without charging any fee at the time of sale of the covered product or at the time the unwanted products from residential sources are delivered or collected for disposal; and
- operate the product stewardship program in accordance with the product stewardship plan as approved by the WSBP and applicable statutes and rules.

Product Stewardship Plan

A producer or group of producers who operates or wishes to operate a product stewardship program, or a stewardship organization that operates or wishes to operate a product stewardship program on a producer's behalf, must submit a plan to the WSBP that includes:

- contact information;
- performance goals;
- design improvements (including how the formulation, prescribing practices, packaging, and distribution of covered products and their packaging might be improved to reduce waste, reduce toxicity, and reduce environmental impacts);
- a collection system;
- a handling and disposal system; and
- how the product stewardship program addresses licensing requirements.

Each plan submitted must include information in addition to the plan itself that readily identifies through a table or similar means how the requirements of the act and any rules adopted to implement the act have been met in relation to the content of the plan.

If the WSBP is satisfied that a proposed product stewardship plan complies with this bill and any rules adopted to implement, the WSBP must approve the product stewardship plan. The plan must be approved before granting a license.

A plan submitted to the WSBP must be available to the general public through the Internet. Information within a plan that is deemed by the WSBP as potentially creating a security risk may not be posted. All plans must be submitted to the WSBP by January 1, 2009. The WSBP must review each plan in consultation with the DOE.

Reporting

After January 1, 2009 each new producer and each producer new to Washington must submit a plan to the WSBP or join an approved plan prior to initiating sales in or into this state.

On or before June 30, 2011, and in each subsequent year, every person operating a product stewardship program must prepare and submit to the WSBP a written annual report describing the activities of the product stewardship program during the previous reporting period.

All reports submitted to the WSBP must be made available to the DOE for review.

A report submitted to the WSBP must be made available to the general public through the Internet. Information within a report that is deemed by the WSBP as potentially creating a security risk may not be posted.

Product Disposal

Each product stewardship program must dispose of all unwanted products from residential sources at a hazardous waste facility but otherwise retains all other generator exemptions for household hazardous waste, except product stewardship programs may petition the DOE for approval to use final disposal technologies that provide superior environmental and human health protection than provided by current hazardous waste disposal technologies for drugs, if and when those technologies are proven and available.

Producers and stewardship organizations are encouraged to invest in research to find disposal technologies that provide superior protection to human health and the environment beyond that provided by current hazardous waste disposal technologies.

The WSBP must invite comments once a year from health care facilities, health care practitioners, pharmacists, local governments, and citizens to report their satisfaction with the services provided by a product stewardship program. This information must be used by the WSBP in reviewing plan updates and revisions.

Compliance

If the WSBP determines that a product stewardship program is not being operated in accordance with the requirements of this bill and rules adopted to implement this bill, or if the WSBP determines that there is an imminent danger to the public, the WSBP may:

- amend the approval of the plan by clarifying terms or conditions to ensure full implementation of the plan; or
- suspend or cancel the approval of the plan.

If the WSBP determines that it is necessary in order to protect the public from imminent danger, the WSBP may immediately amend, suspend, or cancel an approval.

Producers who are participating in an approved product stewardship program must be listed on the WSBP's Web site. The WSBP must list producers who have been identified as noncompliant on the WSBP's Web site.

Drug wholesalers must check the WSBP's Web site to determine if producers of products they are wholesaling in or into the state are in compliance. If the drug wholesaler is unsure of the status of the producer or believes the producer is not in compliance with this bill, the drug wholesaler must contact the WSBP to determine the producer's status.

The WSBP must send a written warning and a copy of the requirements of this bill to a producer who is not a part of an approved product stewardship program and whose covered product is being sold in or into the state. The WSBP must also send written notification to a drug wholesaler known to be selling such a product in or into the state.

Producers who are not participating in an approved product stewardship program and whose covered products continue to be sold into the state 60 days after receipt of the written warning, and drug wholesalers who sell products from producers who are not participating in an approved product stewardship program 60 days after receipt of the written warning, must pay a fine of \$10,000 per day of noncompliance, beginning 60 days after receipt of the written warning.

The WSBP is authorized to waive or reduce the fine if the producer becomes compliant, to protect public health, or for any other reasons the WSBP determines to be justified.

The WSBP must send a written warning under this bill to a producer who operates a product stewardship program, or a person who operates a product stewardship program on a producer's behalf, who fails to submit a plan, plan revision, or annual report as required in this bill. The written warning must include compliance requirements and notification that the compliance requirements must be met within 60 days. If the compliance requirements are not met within 60 days, the producer or other person who operates a product stewardship program on the producer's behalf must be assessed a \$10,000 penalty.

A violation of this bill is a misdemeanor, and each calendar day of operation is deemed a separate offense.

The DOE, or its designee, is authorized to inspect, audit, or review the audits of disposal facilities that are utilized to fulfill the requirements of a product stewardship program.

Rules and Standards

The WSBP and the DOE are authorized to adopt any rules necessary to enact, implement, administer, and enforce this bill.

If rules are found to be necessary, the WSBP and the DOE are each authorized to require the producer or group of producers or a stewardship organization to develop and pay all costs of developing draft rules for submittal to the WSBP or DOE that may be used by the agencies if found to be suitable as a starting point for development of official rules.

If requested to develop draft rules, the producer or group of producers or stewardship organization must convene a diverse stakeholder group to review and provide input for draft rule development in meetings open to the public. Recommendations made under draft rules must include the rationale that supports the recommendation.

The WSBP and the DOE may use any draft rules that are submitted as they deem appropriate to facilitate official rule development.

By June 2012 the WSBP must establish mandated performance standards and recovery rates for the fourth and subsequent program years and must establish a fine system for those producers and product stewardship programs that do not attain the mandated standards and rates.

By December 2011 the producer or group of producers or a stewardship organization must develop and pay all costs for developing a report for submittal to the WSBP that recommends and explains the rationale for recommended performance standards, recovery rates, and a fine system for non-attainment of mandated standards and rates for the fourth and subsequent program years.

The producer or group of producers or stewardship organization must convene a diverse stakeholder group to review and advise regarding the development of the report in meetings open to the public.

The WSBP may use this report as it deems appropriate to facilitate establishment of performance standards, recovery rates, and a fine system.

By December 31, 2013 the WSBP must report to the appropriate committees of the Legislature concerning the status of the product stewardship program and recommend legislative action or modification to the rules, if necessary.

Pharmaceutical Product Stewardship Programs Account

The Pharmaceutical Product Stewardship Programs Account (Account) is created in the custody of the State Treasurer:

- All fines and penalties collected under this act must be deposited into the Account.
- Expenditures from the Account may be used only for the administration of this bill.
- Only the WSBP may authorize expenditures from the Account.

- The Account is subject to allotment procedures, but an appropriation is not required for expenditures.

Product Stewardship Program Promotion

The Product Stewardship Program (Program) must promote the use of the program and the proper disposal of drugs so that collection options are widely understood by customers, pharmacists, retailers of covered products, and health care practitioners including doctors and other prescribers.

The Program must establish a toll-free telephone number and Web site where collection options will be publicized and prepare educational and outreach materials describing where and how to return unwanted drugs to the Program. These materials must be provided to pharmacies, health care facilities, and other interested parties.

Health care practitioners, health care facilities, pharmacists, drug wholesalers, drug retailers, waste companies, local and state agencies, charity organizations, and others are also encouraged to promote the proper disposal of drugs and use of product stewardship programs.

Pharmacies must provide information to consumers describing where and how to return unwanted drugs to a product stewardship program by providing a toll-free telephone number and Web site established by the Program. Pharmacies must also provide educational materials provided by product stewardship programs.

Enforcement

The WSBP has the power to refuse, suspend, or revoke the license of any pharmaceutical product stewardship program, or any other WSBP licensed entity upon proof that:

- the license was procured through fraud, misrepresentation, or deceit; and
- the licensee has violated or has permitted any employee to violate any of the laws of this state or the United States relating to drugs, controlled substances, cosmetics, or nonprescription drugs, or has violated any of the rules and regulations of the WSBP of pharmacy or has been convicted of a felony.

Upon a finding, after hearing, that a producer or a license holder or licensed entity, or any person in the employ of the licensee has violated the laws of this bill, this state, or the United States relating to drugs, controlled substances, cosmetics, or nonprescription drugs, or has violated any of the rules of the WSBP, or has been convicted of a felony, after the time of licensing, the WSBP has the power to impose a \$10,000 fine per violation.

Licensing

The producer, group of producers, or stewardship organization wishing to operate a pharmaceutical product stewardship program must apply for a no fee license of location from the WSBP that entitles the producer, group of producers, or stewardship organization to operate a pharmaceutical product stewardship program.

The producer, group of producers, or stewardship organization may operate the pharmaceutical product stewardship program upon presentation of evidence as required and accepted by the WSBP to demonstrate competence and knowledge to operate the Product Stewardship Program.

A license may not be granted prior to approval of the product stewardship plan by the WSBP and the WSBP must require as part of the license application:

- written operating policies and procedures meeting WSBP guidelines;
- procedures for periodically conducting background checks for firm officers and employees; and
- a specific written description of the business activities and limitations of practice.

Licenses obtained under this section only allow for the collection and disposal of drugs. The license activity is limited to the specific activity and limits as approved by the WSBP application. The respective license is for a specified period ending on the date to be determined by the Secretary of Health, and at the specified location.

Each owner must, at the time of license renewal, file with the Department of Health on an application provided by the WSBP a declaration of ownership and location.

Failure to comply with declaration of ownership and location requirements is a misdemeanor, and each day in noncompliance is deemed a separate offense.

This bill takes effect July 1, 2008.

Substitute Bill Compared to Original Bill:

The substitute bill:

- adds generic drugs to products covered under the bill;
- adds requirements that the producer or group of producers or a stewardship organization:
 - highlight how requirements of the bill and any adopted rules have been met in relation to the product stewardship plan;
 - develop draft rules involving stakeholders and the public for use by the agencies as appropriate to facilitate development of official rules;
 - submit a report after involving stakeholders and the public that recommends performance standards, recovery rates, and a fine system for nonattainment of mandated standards and rates for use by the WSBP as appropriate to facilitate development of performance standards, recovery rates, and a fine system;
- removes encouragement to report on non compliant producers;
- removes the \$25,000 penalty provision; and
- clarifies that licenses obtained only allow for the collection and disposal of drugs.

Appropriation: None.

Fiscal Note: Preliminary fiscal note available. Fiscal note requested on substitute bill on January 31, 2008.

Effective Date of Substitute Bill: The bill takes effect on July 1, 2008.

Staff Summary of Public Testimony:

(In support) Disposal of residential drugs is both a safety issue and an environmental issue. People do not know what to do with the drugs they no longer need and they don't have a good option, but they need to do something. The cumulative amount of these drugs is significant. Many of these drugs end up in the environment with adverse affects on wildlife. A U. S. Drug Enforcement Administration waiver is needed to handle narcotics. There is a pilot program underway in the state that is doing well. Unwanted drugs are a danger for unintentional poisonings and for kids getting high. Manufacturers should take responsibility and pay for a medicine return program. A medicine return program removes the cost from the taxpayer and puts it in the relationship between the seller and consumer. Hazardous waste drop off facilities are not suitable for drug disposal due to lack of facilities and untrained staff. This bill offers a non-prescriptive, free market approach expected to cost only 1 - 2 cents per medicine sold, while for comparison \$1.2 billion is spent on drug advertising in the state. Companies that produce the medicines have a responsibility to participate in responsible disposal to ensure communities and families are safe. This bill is a practical and sensible effort. It is cheaper to prevent cleanup than to do the cleanup. A better public education effort is needed. This could be a "hero" bill for pharmaceutical companies to show they care about product stewardship. Generic drugs need to be included as part of the bill.

(In support with concerns) Drug take-back programs are a good idea for all the reasons mentioned. To get where this bill needs to go a U. S. Drug Enforcement Administration waiver is needed to allow collection of controlled substances. Agencies and the Governor's Office have requested a waiver. The State Board of Health supports the concept but does have concerns about the resources necessary for implementation. A funding source needs to be identified. The scope and volume of drugs require high security around diversion and misuse. There are a large number of producers which will require a significant workload for which a funding source is not currently identified.

(Opposed) It is not clear how responsibility for costs is assigned. Generic prescriptions should be included in the bill. The evidence is not showing that problems diminish with drug take-back programs. Clark County does have a drug disposal option at their household hazardous waste facility. This bill may be premature in that the pilot program is not out in full operation and the track record is not good with other drug take-back programs. We should take greater advantage of programs such as the Drug Abuse Resistance Education; the Partnership for a Drug Free America; and the Partnership for Safe Medication Use. If implemented, the bill will only take care of 0.10 percent of the drugs that end up in the environment; remaining drugs are passed into the waste stream from excretions.

Persons Testifying: (In support) Representative Morrell, prime sponsor; Dave Galvin, Local Hazardous Waste Management Program, King County; Shirley Reitz, Group Health

Cooperative; David Stitzhal, Northwest Product Stewardship Council; Craig Engelking, Sierra Club; Bruce Reeves, Washington State Senior Citizens Lobby; Ken Bulti, LOTT Alliance; Will Perry, Seattle-King County Public Health; Suellen Mele, Washington Citizens Resource Conservation; Karen Bowman, RN, Washington State Nurses Association; Pam Tazioli, Breast Cancer Fund; Blair Anundson, Washington Public Research Interest Group; Leslie Emerick, Washington Hospice and Palliative Care Organization; Heather Trim, People for Puget Sound; and Ed Thorpe, Coalition for Clean Water.

(In support with concerns) Steven Saxe, Department of Health.

(Opposed) Jeff Gombosky, Amgen; and Cliff Webster, Pharmaceutical Research and Manufacturers of America.

Persons Signed In To Testify But Not Testifying: None.